

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Heidi Lopez de Diego et al.	Art Unit :	1624
Patent No. :	7,767,683	Examiner :	Emily Bernhardt
Issue Date :	August 3, 2010	Conf. No. :	6471
Serial No. :	10/568,572		
Filed :	August 14, 2006		
Title :	HYDROGEN SUCCINATE SALTS OF TRANS-4-((1R,3S)-6-CHLORO-3-PHENYLINDAN-1-YL)-1,2,2-TRIMETHYLPYPERAZINE AND THE USE AS A MEDICAMENT		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO DECISION ON REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT

In a Decision on Request for Reconsideration of Patent Term Adjustment ("Decision") dated February 24, 2011, the United States Patent and Trademark Office ("the Office") partially granted Patentee's Application For Patent Term Adjustment Under 37 C.F.R. § 1.705(d) filed on October 1, 2010 ("Application for PTA"). The present response is filed timely within the 30 day period for reply provided by the Decision.

I. Pending Civil Action in the U.S. District Court for the District of Columbia

Patentee filed a civil action against the Office in the U.S. District Court for the District of Columbia on January 28, 2011, requesting correction of the patent term adjustment calculation for the present patent (copy of complaint enclosed).

II. The Office Incorrectly Assessed Applicant Delay for the Filing of a Supplemental Application Data Sheet After the Mailing of a Notice of Allowance

Patentee filed a Supplemental Application Data Sheet on June 22, 2010, subsequent to the mailing of a Notice of Allowance. The Office assessed applicant delay for this filing, under 37 CFR 1.704(c)(10), from the date the Supplemental Application Data Sheet was filed until the date the patent issued. In the Application for PTA, Patentee asserted that no applicant delay

CERTIFICATE OF MAILING BY EFS-WEB FILING

I hereby certify that this paper was filed with the Patent and Trademark Office using the EFS-WEB system on this date: March 22, 2011.

should have been assessed with the filing. In the Decision, the Office rejected Patentee's argument. Patentee respectfully requests reconsideration of this issue in view of the following remarks.

The changes requested in the Supplemental Application Data Sheet were the addition of the email address of a practitioner under the address portion of the assignee information section and the change of an inventor's city name under the residence information section. In rejecting Patentee's assertion that no applicant delay should have been assessed for this filing, the Decision focused on the content and form of the Supplemental Application Data Sheet as well as a comparison of the filing to exemplary filings listed in MPEP 2732 as not constituting "failure to engage in reasonable efforts to conclude processing or examination of an application" under 37 CFR 1.704(c)(10). The Office concluded that the Supplemental Application Data Sheet filed in this matter was not in the proper format and does not fall within the "previously identified 'Change of Address' exception." See Decision at page 4.

The issue presented herein is whether the Supplemental Application Data Sheet filed after the mailing of a notice of allowance should have caused the assessment of applicant delay under 37 CFR 1.704(c)(10).

37 CFR 1.704(c)(10) provides that "[s]ubmission of an amendment under § 1.312 or other paper after a notice of allowance has been given or mailed" results in a period of applicant delay equal to the lesser of: (1) the number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper; or (2) four months.

The Office published a document entitled Clarification of 37 CFR 1.704(c)(10) - Reduction of Patent Term Adjustment for Certain Types of Papers Filed After a Notice of Allowance has been Mailed, 1247 Off. Gaz. Pat. Office 111 (June 26, 2001) ("Clarification of 37 CFR 1.704(c)(10)") in an effort to prevent the rigid application of 37 CFR 1.704(c)(10) against every paper filed after the mailing of a Notice of Allowance. In particular, the Office explained that *only* those papers that cause substantial interference and delay in the patent issuance process should trigger applicant delay under 37 CFR 1.704(c)(10).

It should be noted, however, that only certain papers (not all papers), filed after a "Notice of Allowance" is mailed, cause substantial interference and delay in the patent issue process. Therefore, it is the filing of these papers that will be considered a "failure to engage in reasonable efforts" to conclude processing and examination of an application under 37 CFR 1.704. The Office has reviewed many allowed applications (mostly continued prosecution applications (CPAs)) that were filed on or after May 29, 2000, in which the issue fee was paid. The review consistently showed that only certain papers submitted after a "Notice of Allowance" is mailed, interfered with and delayed the patent issue process to such a degree as to constitute a "failure to engage in reasonable efforts" to conclude processing or examination of an application. (Clarification of 37 CFR 1.704(c)(10); emphasis added).

After stating that "only" those papers that substantially interfere with or delay patent issuance should result in an assessment of applicant delay under 37 CFR 1.704(c)(10), the Office provided examples of papers that do not cause delay.

Accordingly, the Office is publishing this notice to provide guidance in interpreting the provisions of 37 CFR 1.704(c)(10) to clarify that submission of certain papers after a "Notice of Allowance," which do not cause substantial interference and delay in the patent issue process, are not considered a "failure to engage in reasonable efforts" to conclude processing or examination of an application. The following are examples of such papers: (1) Issue Fee Transmittal (PTOL-85B), (2) Power of Attorney, (3) Power to Inspect, (4) Change of Address, (5) Change of Status (small/not small entity status), (6) a response to the examiner's reasons for allowance, and (7) letters related to government interests (e.g., those between NASA and the Office). Therefore, the submission of these papers after a Notice of Allowance will not be considered a "failure to engage in reasonable efforts" to conclude processing or examination of an application and would not result in reduction of a patent term adjustment pursuant to 37 CFR 1.704(c)(10). (Clarification of 37 CFR 1.704(c)(10); emphasis added).

The passages reproduced above from the Office's Clarification of 37 CFR 1.704(c)(10) establish that:

(1) only those papers that substantially interfere with or delay the patent issuance process should trigger applicant delay under 37 CFR 1.704(c)(10) and, conversely, those papers that do not substantially interfere with or delay patent issuance should not trigger applicant delay; and

(2) the seven post-allowance papers that are stated by the Office to not trigger applicant delay are examples of such papers and (because the word “example” was used) do not constitute an exhaustive list.

The conduct at issue here (the filing of a Supplemental Application Data Sheet after allowance) is not specifically recited in 37 CFR 1.704(c)(10) as a trigger for applicant delay. As a result, the proper inquiry must be whether the filing of the Supplemental Application Data Sheet constitutes conduct that substantially interferes with the Office's ability to process or examine an application. In contrast, the inquiry presented in the Decision appears to extend no further than a consideration of whether the Patentee's conduct falls within one of the seven specific exceptions listed in the Office's Clarification of 37 CFR 1.704(c)(10) (or the counterpart portion of MPEP 2732).

As an initial matter, Patentee maintains that the Supplemental Application Data Sheet in question is more similar to a Change of Address than it is to any of the eight items listed in MPEP 2732 as constituting “failure to engage in reasonable efforts to conclude processing or examination of an application.” However, and more importantly, there is no evidence of record to suggest that the Supplemental Application Data Sheet filed in the present application substantially interfered with or delayed patent issuance. The patent issued a mere 43 days after the date on which the issue fee was paid and the Supplemental Application Data Sheet was filed, without the Office mailing any action or notice in response to the Supplemental Application Data Sheet. There is no evidence that the processing of the patent to issuance was delayed for *any* amount of time by the filing of the Supplemental Application Data Sheet. In fact, 43 days is understood to be a rapid turnaround from payment of the issue fee to patent issuance (for comparison, the Office is charged for delay under 35 U.S.C. 154(b)(1)(A)(iv) only if it takes more than four months to issue a patent after payment of the issue fee).

The Office's apparent application of 37 CFR 1.704(c)(10) to allow no exceptions other than the seven examples provided in MPEP 2732 reflects a rigidity that is inconsistent with the instruction made by the Office in its Clarification of 37 CFR 1.704(c)(10) that “only” those papers that substantially interfere with patent issuance should result in an assessment of applicant

delay under 37 CFR 1.704(c)(10). Given that the Office did not print the corrected inventor address information provided in the Supplemental Application Data Sheet on the patent or mail an Office action or notice in response to the filing, it is incumbent on the Office to explain what sort of action took place within the Office that is alleged to have interfered with or delayed patent issuance. No evidence of any such delay is evident in the public record of the patent prosecution history. Because the Supplemental Application Data Sheet did not cause any apparent delay in the processing or examination of the application, it cannot be treated as a cause of applicant delay. The 43 days of applicant delay assessed by the Office from June 22, 2010 to August 3, 2010 should be adjusted to 0 days.

III. The Office Incorrectly Excluded from B Delay a Period of Time that was not Consumed by Continued Examination of the Application

As noted above, Patentee filed a civil action against the Office in the U.S. District Court for the District of Columbia on January 28, 2011, requesting correction of the patent term adjustment calculation for the present patent. In addition to the applicant delay assessment challenged in the previous section, the civil action also challenges the calculation of B Delay in the manner summarized below.

Section 154(b)(1)(B)(i) of Title 35 excludes from the calculation of B Delay “any time consumed by continued examination of the application.” The Office erred in the calculation of patent term adjustment by subtracting from B Delay a period of time that was not “consumed by continued examination of the application.” The Office mailed a Notice of Allowance on March 22, 2010, thereby closing examination of the application on that date. Thus, no continued examination took place during the 135 day period from March 22, 2010 (the mailing date of the Notice of Allowance) until August 3, 2010 (the date the patent issued). Accordingly, 135 days of B Delay should have been included in addition to the 144 days accorded by the Director, for a total B Delay of 279 days.

Applicant : Heidi Lopez de Diego et al.
Patent No. : 7,767,683
Issued : August 3, 2010
Serial No. : 10/568,572
Filed : August 14, 2006
Page : 6 of 6

Attorney's Docket No.: 27507-0163001 / 453-US-PCT

Revised Statement of Patent Term Adjustment

In consideration of the events described above, Patentee respectfully submits that the patent term adjustment calculation of 112 days proposed in the Decision is incorrect. Patentee requests reconsideration of the patent term adjustment in the following manner:

- 1) Total Office Delay should be calculated as 491 days (i.e., the sum of 212 days of A Delay and 279 days of B Delay minus 0 days of overlap);
- 2) Total Applicant Delay is 201 days; and
- 3) Total Patent Term Adjustment should be calculated as 290 days.

No fee is believed due. However, if any fee is due, please charge it to Deposit Account No. 06-1050, referencing Attorney Docket Number 27507-0163001.

Respectfully submitted,

Date: March 22, 2011

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

H. Lundbeck A/S
Ottiliavej 9
Valby-Copenhagen
Denmark DK-2500

Plaintiff,

v.

HON. DAVID J. KAPPOS
Under Secretary of Commerce for Intellectual
Property and
Director of the United States Patent and
Trademark Office
Office of General Counsel,
United States Patent and Trademark Office
Madison Building East, Rm. 10B20
600 Dulany Street, Alexandria, VA 22314

Defendant.

Case: 1:11-cv-00233
Assigned To : Roberts, Richard W.
Assign. Date : 1/28/2011
Description: General Civil

COMPLAINT

Plaintiff, H. Lundbeck A/S ("Lundbeck"), for its complaint against the Honorable David J. Kappos, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 7,767,683 ("the '683 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '683 patent be changed from 96 days to 290 days.

2. This action arises under 35 U.S.C. § 154 and the Administrative Procedures Act, 5 U.S.C. §§ 701-706.

JURISDICTION AND VENUE

3. This Court has jurisdiction to hear this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1361; 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. §§ 701-706.

4. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

5. This Complaint is timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

THE PARTIES

6. Plaintiff Lundbeck is a corporation organized under the laws of Denmark, having a principal place of business at Ottiliavej 9, Valby-Copenhagen, Denmark DK-2500.

7. Defendant David J. Kappos ("Director") is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("PTO"), acting in his official capacity. The Director is the head of the agency, charged by statute with providing management supervision for the PTO and for the issuance of patents. The Director is the official responsible for determining the period of patent term adjustment under 35 U.S.C. § 154.

BACKGROUND

8. Heidi Lopez de Diego, Ole Nielsen, Lone Munch Ringgaard, Henrik Svane, Allan Carsten Dahl, Mark Howells, Benny Bang-Andersen, Lars Ole Lyngso, and Sherry Lynn Collier are the inventors of U.S. patent application number 10/568,572 ("the '572 application") entitled "Hydrogen Succinate Salts of Trans-4-((1R,3S)-6-Chloro-3-Phenylindan-1-yl)-1,2,2-Trimethylpiperazine and the Use as a Medicament," which was issued as the '683 patent on August 3, 2010. The claims of the '683 patent are directed to crystalline hydrogen succinate

salts, pharmaceutical compositions, and methods of treatment. The '683 patent is attached as Exhibit A.

9. Plaintiff Lundbeck is the assignee of the '683 patent.

10. Under Section 154 of Title 35 of the United States Code, the Director of the PTO must grant a patent term adjustment in accordance with the provisions of section 154(b), which states, in pertinent part, that "[t]he Director shall proceed to grant the patent after completion of the Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination." 35 U.S.C. § 154(b)(3)(D).

11. In determining patent term adjustment, the Director is required to extend the term of a patent for a period equal to the total number of days attributable to delay by the PTO under 35 U.S.C. §§ 154(b)(1)(A), (B), and (C), as limited by the following: (i) any overlapping periods of PTO delay as specified by 35 U.S.C. § 154(b)(2)(A); (ii) any disclaimer of patent term by the applicant under 35 U.S.C. § 154(b)(2)(B); and (iii) any delay attributable to the applicant under 35 U.S.C. § 154(b)(2)(C).

12. The Director determined that the '683 patent is entitled to 96 days of patent term adjustment pursuant to 35 U.S.C. § 154(b)(3) and issued the '683 patent reflecting that determination.

13. On October 1, 2010, in accordance with 37 C.F.R. 1.705(d), Lundbeck filed an Application for Patent Term Adjustment ("Application for PTA") with the PTO to request correction of the Director's patent term adjustment determination. The Application for PTA is attached as Exhibit B.

14. Section 154(b)(4)(A) of Title 35 provides that “[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such an action.” Section 702 of Title 5 further provides, in pertinent part, that “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.” Having received no reply from the PTO to its Application for PTA, Plaintiff Lundbeck hereby brings the present action for judicial review of the PTO’s calculation of patent term adjustment for the ‘683 patent.

CLAIM FOR RELIEF

15. The allegations of paragraphs 1-14 are incorporated into this claim for relief as if fully set forth herein.

16. The patent term adjustment for the ‘683 patent, as determined by the Director under 35 U.S.C. § 154(b), and as set forth on the face of the patent, is 96 days. The determination of this 96 day patent term adjustment is in error because the PTO, and the Director acting in his official capacity, improperly calculated the length of the PTO delay period defined by 35 U.S.C. § 154(b)(1)(B) and the length of the applicant delay period defined by 35 U.S.C. § 154(b)(2)(C).

17. The correct patent term adjustment for the ‘683 patent is 290 days.

18. Under 35 U.S.C. § 154(b)(1)(A), the correct number of days attributable to PTO examination delay (“A Delay”) is 212 days. The Director correctly calculated the A Delay.

19. Under 35 U.S.C. § 154(b)(1)(B), the correct number of days attributable to application pendency in excess of three years (“B Delay”) is 279 days. The Director incorrectly calculated a length of B Delay of 144 days.

20. Section 154(b)(1)(B)(i) of Title 35 excludes from the calculation of B Delay “any time consumed by continued examination of the application.” The Director erred in the calculation of patent term adjustment by subtracting from B Delay a period of time that was not “consumed by continued examination of the application.” The PTO mailed a Notice of Allowance on March 22, 2010, thereby closing examination of the application on that date. Thus, no continued examination took place during the 135 day period from March 22, 2010 (the mailing date of the Notice of Allowance) until August 3, 2010 (the date the ‘683 patent issued). Accordingly, 135 days of B Delay should have been included in addition to the 144 days accorded by the Director, for a total B Delay of 279 days.

21. Under 35 U.S.C. § 154(b)(2)(C), the correct number of days of applicant delay is 201 days, corresponding to four periods of delay occurring: (i) from August 14, 2008 to November 13, 2008, for a period of 92 days; (ii) from April 23, 2009 to July 16, 2009, for a period of 85 days; (iii) from May 24, 2010 to May 27, 2010, for a period of 4 days; and (iv) from June 2, 2010 to June 21, 2010, for a period of 20 days. The Director incorrectly calculated a total applicant delay of 260 days.

22. The Director correctly calculated periods of applicant delay as occurring: (i) from August 14, 2008 to November 13, 2008; and (ii) from April 23, 2009 to July 16, 2009.

23. The Director incorrectly calculated periods of applicant delay in three separate instances, as explained in each of the following three paragraphs.

24. A Request for Corrected Filing Receipt was filed on May 24, 2010, subsequent to the mailing of a Notice of Allowance. As part of the request for correction of the filing receipt, a Supplemental Application Data Sheet was submitted containing the changes to be made by the correction. The PTO responded to the filing on May 27, 2010, by issuing a Corrected Filing

Receipt. Applicant delay of 4 days for this post-allowance filing is appropriate, for delay occurring between May 24, 2010 (the date on which the post-allowance filing was made) and May 27, 2010 (the date on which the PTO mailed its response). See 37 C.F.R. § 1.704(c)(10). The PTO did not assess any applicant delay for this filing.

25. A Request to Correct Inventorship under 37 C.F.R. § 1.48 was filed on June 2, 2010, subsequent to the mailing of a Notice of Allowance. As part of the request for correction of inventorship, applicants also submitted a declaration by the inventors and a Supplemental Application Data Sheet containing the changes to be made. The PTO responded to this filing on June 21, 2010, by issuing a Corrected Filing Receipt and Response to Rule 312 Communication. The PTO improperly double-counted the single 20 day period (from June 2, 2010 to June 21, 2010) as triggering 40 days of Applicant Delay. Only one period of delay of 20 days is appropriate for this post-allowance filing, since all of the papers filed on June 2, 2010 were related to the Request to Correct Inventorship and the PTO's response on June 21, 2010 constituted a response to all of the papers filed on June 2, 2010. See 37 C.F.R. § 1.704(c)(10). Furthermore, 37 CFR 1.704(c) explicitly prohibits the PTO from double counting periods of applicant delay, stating that "[c]ircumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include the following circumstances, which will result in the following reduction of the period of adjustment set forth in § 1.703 to the extent that the periods are not overlapping." The period of delay from June 2, 2010 to June 21, 2010 should be adjusted from 40 days to 20 days.

26. A Supplemental Application Data Sheet was filed on June 22, 2010, subsequent to the mailing of a Notice of Allowance. The only changes requested on the Supplemental Application Data Sheet were changes to the email address of the practitioner and an inventor's

mailing address. Although the filing of a paper to change an address is not mentioned in 37 C.F.R. § 1.704(c)(10), such a filing is specifically addressed in the section of MPEP 2732 that clarifies the types of papers filed after allowance that are not considered to be a failure to engage in reasonable efforts to conclude processing or examination of an application under 37 C.F.R. § 1.704(c)(10). According to MPEP 2732, papers filed after allowance that are “not considered to be a failure to engage in reasonable efforts to conclude processing or examination of an application [include] ... (4) Change of Address” *Id.* Because the Supplemental Application Data Sheet filed on June 22, 2010 related only to corrections of the practitioner’s email address and an inventor’s mailing address, an assessment of applicant delay for this filing is inappropriate. Furthermore, there is no indication that this post-allowance filing caused any amount of actual delay in the processing of the application or the issuance of the patent (the patent issued in a mere 43 days after payment of the issue fee, without the PTO mailing any notice in response to the Supplemental Application Data Sheet). An applicant submission that does not cause any delay in the processing or examination of an application cannot be treated by the PTO as a cause of applicant delay. The 43 days of applicant delay assessed by the PTO from June 22, 2010 to August 3, 2010 should be adjusted to 0 days.

27. Section 154(b)(2)(A) of Title 35 provides that “to the extent that periods of delay attributable to grounds specified in paragraph [b](1) overlap, the period of any adjustment . . . shall not exceed the actual number of days the issuance of the patent was delayed.” The overlap between the A Delay period and the B Delay period in the prosecution of the ‘683 patent is 0 days. The Director correctly calculated the overlap between the A Delay period and the B Delay period.

28. The '683 patent is not subject to a disclaimer of term. Thus the period of patent term adjustment is not limited under 35 U.S.C. § 154(b)(2)(B).

29. The correct patent term adjustment under 35 U.S.C. §§ 154(b)(1) and (2) is the sum of the A Delay and B Delay (212 days + 279 days = 491 days) minus the number of days of overlap of A Delay and B Delay (0 days) and applicant delay (201 days), for a net correct patent term adjustment of 290 days for the '683 patent.

30. Accordingly, the Director's determination that the '683 patent is entitled to only 96 days of patent term adjustment, as evidenced by the PTO Decision, is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation.

PRAYER FOR RELIEF

Wherefore, Plaintiff demands judgment against Defendant and respectfully requests that this Court enter Orders:

A. Changing the period of patent term adjustment for the '683 patent term from 96 days to 290 days, and requiring the Director to extend the term of the '683 patent by 194 days to reflect the correct 290 day patent term adjustment.

B. Granting such other and future relief as the nature of the case may admit or require and as may be just and equitable.

Dated: January 28, 2011

Respectfully Submitted,



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